



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/600,118

06/20/2003

William W. Cimino

40206.19US01

9143

23552 7590 10/01/2008
MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/600,118 | | CIMINO, WILLIAM W. | |
| | Examiner | | Art Unit | |
| | LAURA A. BOUCHELLE | | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to the claims add the limitation, “the process not being deployed to adjust the rate of delivery of the fluid” and “the signal not being used to adjust the rate of flow of the sterile fluid.” There is no support for this in the specification. The specification discloses that the rate delivery is adjustable, but fails to disclose the means for adjusting the speed. Therefore, there is no support for the device not including a specific means for controlling the rate of delivery.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,6-7,9-13,15-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeldon et al (USPN 4,670,007) in view of Hadzic et al (USPN 5,910,135). Wheeldon discloses a strain gauge sensor (2), a container of sterile fluid (3), a peristaltic pump

Art Unit: 3763

(7), a sterile tubing set (4), a processor (30) and a display (10). See figure 1 and 3:49-56; 4:22,35-39,63-5:11; 5:18-33; and 5:37,46-47,63-64. The device is capable of being used during any type of surgical procedure that would require a rapid administration of fluids including a cosmetic procedure such as lipoplasty. Regarding the pump, the pump has an adjustable speed control based on the weight of the fluid container.

Wheeldon discloses that the processor calculates the actual flow rate and compares that flow rate with the desired flow rate and makes adjustments as necessary. In a situation where the actual flow rate is calculated to be the desired flow rate, no adjustment will be made. Therefore, Wheeldon meets the claim limitation of the processor not being deployed to adjust the fluid flow rate, at least in certain situations.

Wheeldon does not disclose a method for accurately delivering sterile fluids for use in a cosmetic surgery such as lipoplasty or breast implantation that includes a pump that delivers or is capable of delivering fluid within the range of 30 ml/min to 1000 ml/min.

However, Hadzic discloses such a flow rate for intravenous infusion if a high flow rate is needed due to intraoperative bleeding, etc. See 7:45+.

At the time of the invention, it would have been obvious by one skilled in the art to enable the pump of Wheeldon to be adjusted to have a flow rate of 75ml/min. The motivation for the teaching is provided by Hadzic in that a high flow rate may be needed to treat intraoperative bleeding. The incorporation would have been done in order to enhance the performance of the device during a surgical procedure.

Claims 5,8,14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeldon in view of Hadzic. Wheeldon in view of Hadzic meets the claim limitations as described above for claims 1 and 10. Wheeldon in view of Hadzic does not teach the tubing set being made of polyvinyl chloride.

However, at the time of the invention, it would have been obvious by one skilled in the art to make the tubing set from polyvinyl chloride. Applicant has not disclosed that PVC solves a problem, is used for a particular purpose or provides an advantage. Furthermore, PVC is well known in the art of fluid delivery for medical purposes and would have been chosen for its excellent ability to withstand sterilization before use.

Response to Arguments

4. Applicant's arguments filed 9/7/07 have been fully considered but they are not persuasive. Applicant argues that support for the claim amendments is found in the specification. The examiner can find no such support. There certainly is support for the pump rate being adjustable, and for the processor processing the electrical output, but there is no support for the actual limitation that has been added into the claims. Support in the specification for the processor doing one thing is not the same as support for the processor not doing another.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

Application/Control Number: 10/600,118
Art Unit: 3763

Page 6

/L. A. B./
Examiner, Art Unit 3763